UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

GILEAD SCIENCES, INC. and
EMORY UNIVERSITY,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC. and
TEVA PHARMACEUTICAL INDUSTRIES
LIMITED,

Defendants.

Case No. 08-CV-10838 (RJS) (AJP)

FILED ELECTRONICALLY

SECOND AMENDED ANSWER AND COUNTERCLAIM

In response to the numbered allegations of the second amended complaint of plaintiffs Gilead Sciences, Inc. ("Gilead") and Emory University ("Emory"), defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Limited ("Teva") allege as follows:

1. Admitted.

2. Teva is without information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

3. Teva is without information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

4. Admitted.

5. Admitted.

6. Admitted that Teva USA is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Limited. Otherwise denied.

7. Denied.

8. Admitted that this action arises under the patent laws. Otherwise denied.

9. Teva USA does not contest personal jurisdiction solely for purposes of this case. Otherwise denied.

10. Teva USA does not contest personal jurisdiction solely for purposes of this case. Otherwise denied.

11. Admitted.

12. Teva USA admits that it sells certain pharmaceutical products manufactured by Teva Pharmaceutical Industries Limited. Otherwise denied.

13. Teva USA does not contest venue. Otherwise denied.

14. Admitted.

15. Admitted.

16. Teva admits that the ’245 patent is Exhibit A to the complaint, that it issued on November 4, 2003, and that is entitled as recited in this paragraph. Teva admits that the ’245 patent is listed in the Orange Book for Truvada and Atripla tablets. Otherwise denied.

17. Teva admits that the ’396 patent is Exhibit B to the complaint, that it issued on March 9, 2004, and that is entitled as recited in this paragraph. Teva admits that the ’396 patent is listed in the Orange Book for Truvada and Atripla tablets. Otherwise denied.

18. Teva admits that emtricitabine has the recited chemical formula. Otherwise denied.

19. Teva admits that the Truvada label lists the chemical name for emtricitabine. Otherwise denied.

20. Teva admits that the recited persons are named as inventors on the ’245 and ’396 patents. Otherwise denied.

21. Teva is without information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

22. Teva is without information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

23. *See* Teva’s responses to paragraphs 1–14 and 16–22.

24. Teva USA admits that it filed ANDA No. 90-894 for approval to commercially manufacture, use, sell, and import tablets containing 200 mg emtricitabine and 300 mg of tenofovir disoproxil fumarate. Otherwise denied.

25. Denied.

26. Teva USA admits that on or about November 3, 2008, it transmitted the November 3, 2008 Notice Letter to Gilead. Otherwise denied.

27. Teva USA admits that the November 3, 2008 Notice Letter notified Gilead that Teva USA had filed a paragraph IV certification, and included a detailed statement that met all statutory and regulatory requirements. Otherwise denied.

28. Admitted.

29. Denied.

30. Denied.

31. Denied.

32. *See* Teva’s responses to paragraphs 1–14, 16–22, and 24.

33. Denied.

34. Teva USA admits that on or about November 3, 2008, it transmitted the November 3, 2008 Notice Letter to Gilead. Otherwise denied.

35. Teva USA admits that the November 3, 2008 Notice Letter notified Gilead that Teva USA had filed a paragraph IV certification, and included a detailed statement that met all statutory and regulatory requirements. Otherwise denied.

36. Admitted.

37. Denied.

38. Denied.

39. Denied.

40. *See* Teva's responses to paragraphs 1–13 and 15–22.

41. Teva USA admits that it filed ANDA No. 91-215 for approval to commercially manufacture, use, and sell tablets containing 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate. Otherwise denied.

42. Denied.

43. Teva USA admits that on or about March 30, 2009, it transmitted the March 30, 2009 Notice Letter to Gilead. Otherwise denied.

44. Teva USA admits that the March 30, 2009 Notice Letter notified Gilead that Teva USA had filed a paragraph IV certification, and included a detailed statement that met all statutory and regulatory requirements. Otherwise denied.

45. Admitted.

46. Denied.

47. Denied.

48. Denied.

49. *See* Teva's responses to paragraphs 1–13, 15–22, and 41.

50. Denied.

51. Teva USA admits that on or about March 30, 2009, it transmitted the March 30, 2009 Notice Letter to Gilead. Otherwise denied.

52. Teva USA admits that the March 30, 2009 Notice Letter notified Gilead that Teva USA had filed a paragraph IV certification, and included a detailed statement that met all statutory and regulatory requirements. Otherwise denied.

53. Admitted.

54. Denied.

55. Denied.

56. Denied.

57. Denied.

DEFENSES

FIRST DEFENSE: NONINFRINGEMENT

58. The importation, manufacture, use, offer for sale or sale of the product that is the subject of ANDA No. 90-894 would not infringe any valid claim of either of the '245 or '396 patents.

59. The importation, manufacture, use, offer for sale or sale of the product that is the subject of ANDA No. 91-215 would not infringe any valid claim of either of the '245 or '396 patents.

SECOND DEFENSE: INVALIDITY

60. To the extent that any of the claims of the '245 and '396 patents would otherwise cover the manufacture, use, offer for sale or sale of the product that is the subject of ANDA No.

90-894, those claims are invalid for failure to meet the requirements of one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 or 112.

61. To the extent that any of the claims of the ’245 and ’396 patents would otherwise cover the manufacture, use, offer for sale or sale of the product that is the subject of ANDA No. 91-215, those claims are invalid for failure to meet the requirements of one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 or 112.

62. To the extent that any of the claims of the ’245 and ’396 patents would otherwise cover the manufacture, use, offer for sale or sale of the product that is the subject of ANDA No. 90-894, those claims are invalid for obviousness-type double patenting.

63. To the extent that any of the claims of the ’245 and ’396 patents would otherwise cover the manufacture, use, offer for sale or sale of the product that is the subject of ANDA No. 91-215, those claims are invalid for obviousness-type double patenting.

THIRD DEFENSE: LACK OF PERSONAL JURISDICTION

64. There is no personal jurisdiction over Teva Pharmaceutical Industries Limited.

FOURTH DEFENSE: FAILURE TO STATE A CLAIM

65. The complaint fails to state a claim upon which relief may be granted against Teva Pharmaceutical Industries Limited.

COUNTERCLAIM FOR PATENT NONINFRINGEMENT AND INVALIDITY

As a counterclaim, Teva USA alleges as follows:

66. This is a counterclaim for a declaratory judgment of patent noninfringement and invalidity. This counterclaim arises under the patent laws, Title 35, U.S.C., and jurisdiction is based on 28 U.S.C. § 1338(a). The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

67. A case of actual controversy exists as to the infringement and validity of the ’245 and ’396 patents because plaintiffs have brought this action alleging that Teva USA’s importation, manufacture, use, offer for sale or sale of the product that is the subject of ANDA Nos. 90-894 and 91-215 would infringe those patents, and Teva USA has denied infringement and alleges that the claims of the patents are invalid to the extent that they cover the importation, manufacture, use, offer for sale or sale of that product.

68. Teva USA is a Delaware Corporation having a place of business at 1090 Horsham Road, North Wales, PA 19454.

69. On information and belief, Gilead is a Delaware corporation having a place of business at 331 Lakeside Drive, Foster City, CA 94404.

70. On information and belief, Emory is a Georgia corporation having an office at 201 Dowman Drive, Atlanta, GA 30322.

71. On information and belief, Gilead asserts that it owns all substantial rights in the ’245 and ’396 patents.

72. On information and belief, Emory is the owner of the ’245 and ’396 patents.

73. Teva USA repeats and realleges paragraphs 66–71 above.

74. Teva USA’s manufacture, use, sale, or offer for sale of the product that is the subject of ANDA No. 90-894 does not and would not infringe any valid claim of the ’245 patent.

75. Teva USA’s manufacture, use, sale, or offer for sale of the product that is the subject of ANDA No. 91-215 does not and would not infringe any valid claim of the ’245 patent.

76. The claims of the ’245 patent are invalid.

77. Teva USA’s manufacture, use, sale, or offer for sale of the product that is the subject of ANDA No. 90-894 does not and would not infringe any valid claim of the ’396 patent.

78. Teva USA's manufacture, use, sale, or offer for sale of the product that is the subject of ANDA No. 91-215 does not and would not infringe any valid claim of the '396 patent.

79. The claims of the '396 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, defendant Teva USA requests the following relief:

1. A judgment declaring that the Teva USA's importation, manufacture, use, offer for sale or sale of the product that is the subject of ANDA No. 90-894 would not infringe any claim of the '245 and '396 patents.

2. A judgment declaring that the Teva USA's importation, manufacture, use, offer for sale or sale of the product that is the subject of ANDA No. 91-215 would not infringe any claim of the '245 and '396 patents.

3. A judgment declaring that the claims of the '245 and '396 patents are invalid.

4. Attorneys fees and costs of suit.

5. Such other relief as the Court may decide is just and proper.

Dated: October 9, 2009

KENYON & KENYON LLP

s/ James Galbraith

James Galbraith (JG 4451)
Elizabeth A. Gardner (EG 3930)
Michael J. Freno (MF 6969)
One Broadway
New York, New York 10004
(212) 425-7200

CERTIFICATE OF SERVICE

I hereby certify that on October 9, 2009, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

Nicholas M. Cannella (NC 9543)
Colleen Tracy (CT 8377)
Christopher P. Borello (CB 6164)
Fitzpatrick, Cella, Harper & Scinto
30 Rockefeller Plaza
New York, NY 10112
Tel: (212) 218-2100
Fax: (212) 218-2200

Attorneys for Plaintiffs
Gilead Sciences, Inc. and Emory University

s/ Michael J. Freno